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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,732	09/18/2001	Ralf M. Luche	200125.433	9468

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,732	LUCHE ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-98 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-98 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

[1] Claims 1-98 are pending in the application.

[2] Receipt of Information Disclosure Statements (Forms PTO-1449) in Paper Nos. 7 and 8 are acknowledged. Copies of Forms PTO-1449 acknowledging consideration of the cited references will be returned in the first Office action on the merits.

Election/Restrictions

[3] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim(s) 1, drawn to an isolated polypeptide of SEQ ID NO:2 or variants thereof, classified in class 435, subclass 196.

II. Claim(s) 45 and 46, drawn to a DSP-15 substrate trapping mutant that differs from SEQ ID NO:2 including having a substitution at positon 382 or 413 of SEQ ID NO:2, classified in class 435, subclass 196.

III. Claim(s) 50, drawn to an isolated polypeptide of SEQ ID NO:21 or variants thereof, classified in class 435, subclass 196.

IV. Claim(s) 94 and 95, drawn to a DSP-15 alternate form substrate trapping mutant that differs from SEQ ID NO:21 including having a substitution at positon 382 or 413 of SEQ ID NO:2, classified in class 435, subclass 196.

V. Claim(s) 2-14, drawn to an isolated polynucleotide encoding SEQ ID NO:2 or fragments thereof including SEQ ID NO:1, an expression vector, a host cell, an antisense polynucleotide, and a method for producing a DSP-15 polypeptide, classified in class 435, subclass 196.

VI. Claim(s) 51-63, drawn to an isolated polynucleotide encoding SEQ ID NO:21 or fragments thereof including SEQ ID NO:20, an expression vector, a host cell, an

antisense polynucleotide, and a method for producing a DSP-15 alternate form polypeptide, classified in class 435, subclass 196.

VII. Claim(s) 15-17, drawn to an isolated antibody or antigen binding fragment thereof that binds to SEQ ID NO:2 and a pharmaceutical composition thereof, classified in class 424, subclass 130.1.

VIII. Claim(s) 64-66, drawn to an isolated antibody or antigen binding fragment thereof that binds to SEQ ID NO:21 and a pharmaceutical composition thereof, classified in class 424, subclass 130.1.

IX. Claim(s) 18-21, drawn to a method for detecting DSP-15 expression using an antibody or antigen binding fragment thereof, classified in class 435, subclass 7.1.

X. Claim(s) 67-70, drawn to a method for detecting DSP-15 alternate form expression using an antibody or antigen binding fragment thereof, classified in class 435, subclass 7.1.

XI. Claim(s) 22-25, drawn to a method for detecting DSP-15 expression using an antisense polynucleotide, classified in class 435, subclass 6.

XII. Claim(s) 71-74, drawn to a method for detecting DSP-15 alternate form expression using an antisense polynucleotide, classified in class 435, subclass 6.

XIII. Claim(s) 26-29 and 47-49, drawn to a method for screening an agent that modulates DSP-15 activity or interacts with DSP-15 by contacting a candidate agent with a polypeptide, classified in class 435, subclass 21.

XIV. Claim(s) 75-78 and 96-98, drawn to a method for screening an agent that modulates DSP-15 alternate form activity or interacts with DSP-15 alternate form by contacting a candidate agent with a polypeptide, classified in class 435, subclass 21.

XV. Claim(s) 30-32 and 42, drawn to a method for screening an agent that modulates DSP-15 activity by contacting a candidate agent with a DSP-15 promoter, classified in class 435, subclass 6.

XVI. Claim(s) 79-81 and 91, drawn to a method for screening an agent that modulates DSP-15 alternate form activity by contacting a candidate agent with a DSP-15 alternate form promoter, classified in class 435, subclass 6.

XVII. Claim(s) 33 and 36-39, drawn to a method for modulating a proliferative response in a cell by contacting a cell with an agent that modulates DSP-15 activity, classified in class 435, subclass 196.

XVIII. Claim(s) 82 and 85-88, drawn to a method for modulating a proliferative response in a cell by contacting a cell with an agent that modulates DSP-15 alternate form activity, classified in class 435, subclass 196.

XIX. Claim(s) 34 and 36-39, drawn to a method for modulating differentiation of a cell by contacting a cell with an agent that modulates DSP-15 activity, classified in class 435, subclass 196.

XX. Claim(s) 83 and 85-88, drawn to a method for modulating differentiation of a cell by contacting a cell with an agent that modulates DSP-15 alternate form activity, classified in class 435, subclass 196.

XXI. Claim(s) 35-41, drawn to a method for modulating survival of a cell by contacting a cell with an agent that modulates DSP-15 activity, classified in class 435, subclass 196.

XXII. Claim(s) 84-90, drawn to a method for modulating survival of a cell by contacting a cell with an agent that modulates DSP-15 activity, classified in class 435, subclass 196.

XXIII. Claim(s) 43 and 44, drawn to a method for treating a patient afflicted with a disorder associated with DSP-15 activity by administering an agent that modulates DSP-15 activity, classified in class 514, subclass 789.

XXIV. Claim(s) 92 and 93, drawn to a method for treating a patient afflicted with a disorder associated with DSP-15 alternate form activity by administering an agent that modulates DSP-15 activity, classified in class 514, subclass 789.

[4] The inventions are distinct, each from the other because:

[5] The polypeptides of Groups I-IV are structurally distinct, elicit different antibodies, and no single polypeptide of Groups I-IV would render any of the others obvious to one of ordinary skill in the art.

[6] The polynucleotides of Groups V and VI are structurally distinct, encode structurally distinct polypeptides, and neither of the polynucleotides of Groups V or VI would render the other obvious to one of ordinary skill in the art.

[7] The antibodies of Groups VII and VIII are structurally distinct, bind structurally distinct polypeptides, and neither of the antibodies of Groups VII or VIII would render the other obvious to one of ordinary skill in the art.

[8] The polynucleotides of Groups V and VI, the polypeptides of Groups I-IV, and the antibodies of Groups VII and VIII each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotide(s) of Group(s) V and VI have other utility besides encoding polypeptides such as being used as hybridization probes, the polypeptide(s) of Group(s) I-IV can be made by another method such as purification from the natural source or chemical synthesis, and the antibodies of Group(s) VII and VIII can be made by a protein other than the polypeptide(s) of Group(s) I-IV such as by purification from the natural source or by chemical synthesis.

[9] The polynucleotide(s) of Group(s) V and VI are unrelated to the method(s) of Group(s) IX, X, and XIII-XXIV as they are neither used nor made by the method(s) of Group(s) IX, X, and XIII-XXIV.

[10] The polynucleotide(s) of Group(s) V and VI are related to the methods of Groups XI and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide(s) of Group(s) V and VI can be used for protein expression.

[11] The polypeptide(s) of Group(s) I-IV are unrelated to the method(s) of Group(s) XI, XII, XV, XVI-XXIV as they are neither used nor made by the method(s) of Group(s) XI, XII, XV, XVI-XXIV.

[12] The polypeptide(s) of Group(s) I-IV and the methods of Groups IX, X, XIII, and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide(s) of Group(s) I-IV can be used as antigens in the production of antibodies.

[13] The antibodies of Group(s) VII and VIII are unrelated to the method(s) of Group(s) XI-XXIV as they are neither used nor made by the method(s) of Group(s) XI-XXIV.

[14] The antibodies of Group(s) VII and VIII and the methods of Groups IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group(s) VII and VIII can be used as affinity reagents in the purification of polypeptides.

[15] The methods of Groups IX-XXIV are independent as they comprise different steps, utilize different products and/or yield different results.

[16] MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of Groups I-XXIV are distinct for the reasons given above, have separate classification, and each of the inventions requires a separate patent and non-patent literature and/or sequence search, restriction for examination purposes is proper.

[17] It is noted that claims 36-39 and 85-88 will be examined only to the extent the claims read on the elected subject matter.

[18] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[19] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

05/28/03